REMARKS

The present amendment and remarks are in response to the Final Office Action mailed July 24, 2008 and follow the submission of a Notice of Appeal filed on December 19, 2008. After entry of this amendment, claims 1 and 4-22 are pending. Claim 1 has been amended without prejudice or disclaimer and finds support *inter alia* in the original claims and in the specification, for example, in Table 3 and Example 8. No new matter has been added.

Applicants respectfully request entry of the above claim amendments as they are believed to put the claims in condition for allowance or, alternatively, in better form for consideration on appeal. Furthermore, the amendment does not present any new issues that require further consideration or search. Thus, entry under 37 C.F.R. § 1.116 is correct.

Rejections Under 35 USC § 112, first paragraph

Claims 1 and 4-22 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking an enabling disclosure. Applicants respectfully disagree and traverse the rejections for the reasons already of record and additionally for the following reasons.

The Examiner alleges that the specification only discloses a tobacco plant transformed with the delta-6 elongase of SEQ ID NO: 3, the delta-6 desaturase of SEQ ID NO: 13, and the delta-5 desaturase of SEQ ID NO: 20, pointing to the label of Figure 2. Contrary to the Examiner's assertion, the specification at page 53, lines 16-17 recites that "100 transgenic tobacco **and linseed plants** are generated, of which approximately 20% synthesize arachidonic acid in the seed." (emphasis added). For 20% of the transgenic plants to produce arachidonic acid in the seed, transgenic plants would need to have been produced. Thus the specification does expressly exemplify not only transgenic tobacco plants but additionally transgenic linseed plants.

The Examiner also contends that it is unclear how the constructs and methods of the Abbadi *et al.* reference (hereinafter "Abbadi") provided with the last response (Amendment and Reply Under 37 CFR § 1.111 dated April 24, 2008) relate to those disclosed in the present specification. As also explained in the previous response, Construct C of Figure 2 on page 2736

of Abbadi corresponds to the triple expression construct pARA2 of the present application (see Table 3 at page 47), which is the expression cassette used in Example 8 (see specification at page 53). Abbadi used this triple expression construct for transformation of tobacco and linseed. The results presented in the Figures in Abbadi are from tobacco and/or linseed transformants transformed with this construct, *i.e.* Construct C corresponding to pARA2 of the present application. Abbadi therefore discloses expression of a construct of the present specification in tobacco and linseed. (Abbadi at page 2736, Figure 2, Construct C). Abbadi further discloses production of two C20 fatty acids in tobacco and four C20 fatty acids in linseed through expression of these genes (see Abbadi at page 2737, Figure 4). Thus, the specification not only provides examples, but sufficient guidance for one skilled in the art following the teachings of the specification, as evidenced in Abbadi, for identifying genes, making expression constructs, and expression of the constructs resulting in the desired fatty acid profiles in several plant species.

The Examiner additionally argues that Broun *et al.* (hereinafter "Broun") teaches which amino acid substitutions can be made in a delta-12 desaturase but does not teach the essential amino acids for delta-6 desaturases, delta-5 desaturases or for delta-6 elongases. Applicants respectfully disagree with the Examiner's interpretation of Broun. Rather Broun teaches that it is routine and well within the skill of one skilled in art to align sequences, to identify conserved residues and motifs, and thus to know where and where not to effect substitutions. Furthermore, whether or not Broun teaches which are the essential amino acids for delta-6 desaturases, delta-5 desaturases or for delta-6 elongases is not relevant to the question of enablement, but rather it is whether the specification teaches one skilled in the art how to make and use the invention. From the teachings of Broun and the detailed guidance of the specification, one of skill in the art when aligning various enzymes would readily be able to identify conserved residues and motifs, and know where and where not to effect substitutions. See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Some experimentation, even a considerable amount, is not "undue" if, *e.g.*, it is merely routine, or if the specification provides a reasonable amount of guidance as to the direction in which the experimentation should proceed, which the present specification clearly does as also evidenced in Abbadi.

The Examiner further asserts that the specification provides only one limited working example in tobacco for one gene construct, while the claims are drawn to a multitude of possible gene constructs that may or may not comprise a delta-5 desaturase. Applicants strongly disagree. As previously explained, compliance with the enablement requirement does not turn on whether an example is disclosed. See MPEP § 2164.02. There has never been a requirement that every species encompassed by a claim must be disclosed or exemplified in a working example. *In re Angstadt*, 537 F.2d 498 (CCPA 1976). Moreover, the specification provides several examples of constructs with multiple desaturases/elongases, for example, in Table 3 at page 47. The specification also provides examples of desaturases and elongases by GenBank Accession No. at page 47, lines 28-31, which can be used in the expression constructs. Additionally, the specification exemplifies expression of a three gene construct in both tobacco and linseed as explained above (see Example 8, at page 53, lines 12-17). Furthermore, the routine nature of the experimentation required to make and use the claimed invention has additionally been demonstrated in Abbadi and further in Broun. Nevertheless, in order to expedite prosecution, the claims have been amended without prejudice or disclaimer. In light of the amendment, the Examiner's assertion is rendered moot.

In light of the comments already of record and those above, Applicant's attorney respectfully reminds the Examiner that the representations in the specification as to the manner of making and using the claimed invention must be taken as in compliance with the first paragraph of 35 U.S.C. §112, unless there is objective evidence or scientifically based reasoning inconsistent with the specification. *See In re Marzocchii and Horton*, 169 U.S.P.Q. 367 (C.C.P.A. 1971). "It is the Patent Office's burden to present evidence that there is some reason to dispute the enablement provided in the specification. Unsupported speculation or conjecture on that the invention "might not work" will not support a rejection based on 35 U.S.C. §112, first paragraph." *Id.*

As provided herein, Applicant respectfully submits that the art and the specification provide ample guidance and predictability for the present claims and the Examiner has not presented the evidence necessary to dispute the enablement provided in the instant specification.

Accordingly, the Patent Office has not met its burden and reconsideration and withdrawal of the enablement rejection is requested.

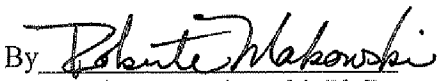
CONCLUSION

For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Applicants respectfully request entry of the above claim amendments as they are believed to put the claims in condition for allowance or, alternatively, in better form for consideration on appeal.

This response is filed within the two-month period for response following the filing of a Notice of Appeal on December 19, 2008. No fee is believed due. However, if a fee is due, please charge our Deposit Account No. 03-2775, under Order No. 12810-00043-US from which the undersigned is authorized to draw.

Respectfully submitted,

By 

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